

Template for the cover letter for the submission of PSURs under the EU PSUR synchronisation scheme, version 24-06-2008

Subject: Submission of the PSUR(s) under the EU PSUR synchronisation scheme for <Product Name(s)>, Procedure Number <../H/PSUR/.../...> National Authorisation Number <xxx>

Dear Sir/Madam,

This PSUR is submitted under the EU synchronisation scheme and covers the period dd/mm/yy to dd/mm/yy.

We confirm that this PSUR has been submitted in all Member States in which we hold a marketing authorisation for the relevant product(s). The annexed table contains a full list of authorisations covered by this PSUR.

For communication in respect to assessment of this PSUR please contact

Name:

Email:

Telephone:

[To be included if the relevant product is not authorised in the P-RMS:]

A copy of the table and the contact point details have also been submitted to the P-RMS: <Member State name>

Yours sincerely,

<Name>

<Signature

